IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

DE RODRIGUEZ et al.

Examiner: Chakrabarti, Arun k

Appln. No. 09/764,783

Art Unit: 1655

Filed: 01/17/2001

For: METHOD OF PROCESSING BLOOD SAMPLES IN ORDER TO PRODUCE DNA COMPLEX PATTERNS FOR DIAGNOSTIC APPLICATIONS

* * *

March 5, 2003

SUBSTITUTE APPEAL BRIEF

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

This is an Appeal from the final rejection of all pending claims 1-20 as set forth in the Final Official Action dated 1 July 2001 in the subject application. No claims stand allowed.

STATUS OF CLAIMS

Claims 1-20 are pending in the application. The rejection of claims 1-20 is appealed. Please see Appendix A for a copy of the claims under Appeal.

STATUS OF AMENDMENT

Applicant submitted an Amendment Under under 37 C.F.R. 1.116 with proposed amendments to Claims 1 and 2, and in which claims 7-20 were canceled. The Examiner has not

responded and it is assumed that this Amendment was not entered. It is believed that the changes made in said Amendment, had they been entered, would have avoided this appeal. Applicant also submitted a request for reconsideration of the finality of the last Official Action which has not been considered.

SUMMARY OF INVENTION

The present invention is a method (depicted in FIG. 1 and described at pages 7, lines 6-23 and page 8, lines 1-17) for processing and preparing blood samples 10 that aggregates and deposits the DNA complex in order to form a unique pattern (shown in FIGs. 2-6). The patterns (shown in FIGs. 2-6) can be used as a medical diagnostic tool to identify a change in the body caused by a specific physiological or pathological condition (such as whether a pregnant woman is carrying a male or female fetus as described at page 9, lines 3-23 to page 11, line 4), and page 10, lines 1, or whether a woman has developed breast or cervical cancer as described at page 11, lines 5-23 to page 11, end). Specifically, changes in the body can be identified by comparing these patterns derived before a specific physiological or pathological condition to those derived after the condition. Further, the specific condition causing the change can be determined by identifying and associating the unique pattern after the condition to the specific condition or disease based on comparative appearance (page 12, lines 1-10) . The patterns aid in the determination of, among other things, the sex of a human fetus within a few days after conception, and the presence of a cancerous condition in the earliest stage of the disease. The

method has the ability to help in detecting changes in the body during the early stages of a physiological or pathological condition without damaging the integrity of the DNA complex.

The above constitutes a concise explanation of the invention defined in claims 1-20 involved in the Appeal.

SUMMARY OF PROSECUTION HISTORY

By First Official Action dated Nov. 23, 2001, the Examiner rejected claims 1-10 under 35 U.S.C. 112, first paragraph, as being indefinite. The Examiner asserted that the patent application's "specification does not reasonably provide enablement for identifying any change in the body of a human being caused by any physiological or pathological condition. The Examiner argued that the "specification provides no guidance regarding methods for identification of any other change in the body of a human being caused by other physiological or pathological condition and no guidance has been provided to detect DNA [complex] patterns in male patients." The Examiner concludes that it is "highly unpredictable whether or what other diseases would be detected by identifying DNA [complex patterns] extracted from blood". A telephone interview ensued during which Applicant';s prior attorney and the Examiner had reached a complete understanding (at least to Applicant's point of view). Nevertheless, the Examiner issued a final Official Action dated July 1, 2002, which essentially held fast to the initial rejection and ignored the interview. Applicant's again filed a Proposed Amendment under 37 C.F.R. 1.116 with proposed changes to Claims 1 and 2, and in which claims 7-20 were

canceled. The Examiner has not yet responded to that Amendment and it is assumed that this Amendment was not entered. It is believed that the changes made in said Amendment, had they been entered, would have avoided this appeal. At that time Applicant also submitted a request for reconsideration of the finality of the last Official Action which has not been considered. This was premised on the telephone interview during which the Examiner and Applicant's previous attorney of record had reached agreement as to the scope and content of the claims. The Examiner had indicated directly to Applicant that he was prepared to allow the claims with proposed amendments. Applicant duly made the proposed amendments and submitted a formal Response, but rather than allowing the claims as had been indicated they were rejected again for exactly the same reasons. The Examiner's about-face deprived Applicant of the opportunity to freely make the current proposed amendments, Applicant is desirous of making the proposed claim changes obligatory, and not discretionary as per final rejection.

RELATED APPEAL PROCEEDINGS

None

ISSUES

There are three categorical issue set forth as follows:

1. Whether the claims are indefinite under 35 U.S.C. §112, (first paragraph) because the specification fails to enable them?

2. Whether claims 1-20 are supported by adequate written description under 35 U.S.C. § 112, first paragraph.

3. Whether claims 1-6 and 9-20 are clear and definite under 35 U.S.C. § 112, second paragraph.

GROUPING OF CLAIMS

As noted above, all presently considered claims 1-20 have been rejected in view of the same general grounds for rejection which the appellant contests. The appellant hereby states that the rejected claims stand and fall together.

APPELLANTS' ARGUMENT

1. Claims 7-20 are enabled under 35 U.S.C. § 112, first paragraph.

The Examiner argues that the "specification provides no guidance regarding methods for identification of any other change in the body of a human being caused by other physiological or pathological condition and no guidance has been provided to detect DNA [complex] patterns in male patients." The Examiner concludes that it is "highly unpredictable whether or what other diseases would be detected by identifying DNA [complex patterns] extracted from blood," and arrives at this conclusion based upon six (6) facts. Applicant contends that the present invention is a *qualitative* approach to processing a blood sample and for using it to detect a change in the

body of a human being caused by a pathological condition. It is not quantitative. Against this background, each of the Examiner's "facts" are discussed in turn:

(A) Reproducible DNA patterns.

The Examiner states that DNA patterns, even from the same pregnant woman, are not reproducible as shown in Figures 2A - 3E of the specification. Applicants respectfully submit that the Examiner has misconstrued the invention disclosed in the specification. With regard to Figures 2A - 2E, those figures comprise the DNA complex patterns of different pregnant woman at varying stages of pregnancy, from six (6) weeks to ten (10) weeks, and Figure 2F sets forth the pattern formed from a pregnant woman carrying twins. The DNA complex patterns from the same woman generally are reproducible. Indeed, Applicants' experiments with pregnant women and nonpregnant women also revealed that the DNA complex patterns for any given blood sample from the same person will exhibit practically identical shapes. In any case it is not the uniformity of such patterns that matters but the visual differences caused by a pathological condition.

Applicants do not disclose nor claim the ability to form patterns of DNA which has been separated from its nucleoprotein complex. Rather, applicants' invention includes the recognition that the patterns formed from DNA and its associated nucleoprotein complex ("DNA complex") can be used to determine the sex of a fetus within just a few weeks after the inception of pregnancy. As described in the specification (page 10, line 9 - page 11, line 4), the patterns of

DNA complex from women carrying a female fetus are readily distinguishable from the patterns formed from women carrying a male fetus. The patterns formed from women carrying a female fetus exhibit "a single and approximately circular or polygonal ring shape" (page 10, lines 17 18). In contrast, the patterns formed from women carrying a male fetus exhibit a "generally linear pattern, or a linear pattern in combination with one or more elongated or collapsed ring patterns" (page 11, lines 1-2). Accordingly, the invention's ability to detect the sex of a fetus is based upon the comparison of the patterns formed by the DNA complex of a woman carrying a female fetus to the patterns formed by the DNA complex of a women carrying a male fetus. Circular or polygonal shaped patterns indicate a female fetus, and linear or elongated ring patterns indicate a male.

Thus, the method of the present invention, for any given blood sample, is highly reproducible. But, it is equally important that applicants have experimentally established that the DNA complex patterns from women carrying a female fetus are easily distinguished from the male fetus patterns.

(B) Correlation between physiological or pathological conditions and DNA complex patterns.

Next, the Examiner asserts that there is no correlation between the physiological or pathological conditions and the DNA complex pattern. Again, the Examiner has misconstrued the invention. With regard to a pregnant woman, the correlation is the comparison of the DNA complex pattern to the two predominate patterns that have been established by using the present

invention to process the blood of approximately 1,000 pregnant women. If the pattern is circular or polygonal in shape, the fetus is a female; if the pattern is linear or elongated in shape, the fetus is a male. With regard to pathological conditions, the correlation is the comparison of the DNA complex pattern to the pattern of a healthy person. As disclosed in the specification, Figure 4 is a representation of a typical pattern formed from the blood of a healthy person, and is based upon using the present invention to process the blood of approximately 300 healthy women and 300 healthy men. The experiments revealed that healthy persons exhibit DNA complex patterns that consist of linear strands that are smooth or are circular in shape and smooth. On the other hand, the DNA complex patterns of women with breast or cervical cancer consist of strands that contain beaded segments and branches (Figure 5; breast cancer) or contain a loop and branches (Figure 6; cervical cancer).

(C) SEM value.

The Examiner further criticizes the specification for failure to disclose a Scanning Electron Microscope valve in order to quantify the DNA pattern. As noted above, however, the present invention does not disclose a method of isolating a DNA molecule. Rather, the patterns that are formed by utilizing the inventive method comprise an aggregation of countless DNA molecules and an associated nucleoprotein complex. Further, the patterns are visible under magnification of an ordinary optical microscope. The application does not attempt to disclose and claim a quantitative or numerical method of detecting changes in DNA molecules. It is purely qualitative: a *qualitative* analysis which provides a method of detecting the sex of a fetus

and a change in the body of a human being who has been exposed to a pathological condition. The change in the body is not detected by quantitatively measuring changes in a nearly invisible DNA molecule, but, in the case of a disease, the change is detected by comparing the pattern of aggregated DNA complex of a healthy person to the pattern of someone who has a significant disease. Not only is an SEM value inappropriate in the present case, but by definition there can be no SEM value due to the qualitative underpinnings. In the case of pregnancy, the inventive method is able to determine the sex of the fetus by comparing the DNA complex pattern to the patterns formed from the blood of women carrying male and female fetuses.

(D) Experimental control.

The Examiner cites the lack of control (i.e., a normal DNA pattern) for an additional reason why the results of the invention are unpredictable. To the contrary, the specification does disclose operable controls. In the instance of cancer, the control is shown in Figure 4, which is illustrative of the DNA complex pattern formed from a healthy person. Further, in the case of the sex of a fetus, the controls are the two (2) distinct patterns formed from the blood of a woman carrying either a male or female fetus.

(E) Phenol extraction.

The Examiner also challenges the disclosure on the basis that the phenol extraction strips off all proteins from the cellular tissue and causes the loss of some nucleic acids. To the contrary, phenol by itself cannot strip off all of the nucleoprotein complex. In order for the

phenol to do so, the tissue must initially be treated with protease (e.g., a histone or histo protein). The present invention does not include this step.

(F) Changes of DNA structure within white blood cell.

The Examiner states that the DNA structure would be expected to change depending on the phase and development of white blood cells and implies that the present inventor does not disclose a method of quantifying the change. But the present invention is not directed to identifying the transient changes to the DNA structure related to cell growth. Rather, the present invention relies, in part, upon the fact that the DNA structure changes as part of a rearrangement process which takes place in bone marrow and which has been shown to be critical to the production of a vast variety of white blood cells with each variety containing a uniquely rearranged DNA structure. What is significant to the present invention is that after the mature white blood cells enter the blood stream, some of the cells produce specific clones as part of an immunological response to the exposure to an antigen, such as a physiological or pathological condition. If the physiological or pathological condition is significant (e.g., pregnancy or cancer), the immunological response produces large numbers of specific clones which are designed to protect the body from the antigen. Applicants believe that the change in the DNA complex pattern of a healthy person after the person has been exposed to a physiological or pathological condition is most probably due to this substantial increase in the volume of white blood cell clones as compared to the volume of all other white blood cells in the blood. (G. Wu Declaration, 8).

Finally, the Examiner concludes that based upon the unpredictable nature of traditional DNA isolation and analysis, the method of the present invention "will not predictably detect or function to detect any particular disease." Contrary to the Examiner's conclusion, applicants do not claim the ability to predict the existence of a specific disease based upon a correlation to a specific DNA complex pattern produced by using the method disclosed in the specification. Rather, applicants claim that they have identified the essential characteristic of the DNA complex patterns of healthy persons in which their patterns have predominately smooth linear strands or circularly shaped smooth strands. Applicants further claim that their method of processing human blood allows someone skilled in the art to readily recognize changes in the predominately smooth strands by using an optical microscope to detect the presence or absence of beads within a smooth strand, a loop within a strand and/or significant branching coming off of a smooth strand. Applicants' experiments have correlated a beaded strand with some branching to the presence of breast cancer (see Figure 5) and have correlated a looped strand with some branching with cervical cancer (see Figure 6). These results are significant not because a specific DNA complex pattern can, at the present time, be associated to a specific disease, but due to the fact that the method can be used as a diagnostic screen to indicate whether a person is being subjected to a significant pathological condition, warranting further medical evaluation and diagnostic techniques. In other words, the relatively simple blood test described in the specification can be used to tell a person whether or not he or she is healthy. If the test indicates the presence of disease, earlier detection would then be possible using more expensive and invasive techniques like an MRI, a CAT scan and a colonscopy. Naturally, a normal test result would provide a

general sense of well being to the patient, possibly removing a generalized fear that he or she has cancer or some other serious disease.

Concerning the sex of a fetus, however, applicants claim that the sex of a fetus can be readily determined by using the method of the present invention to process the blood of a pregnant woman. As described in detail above, applicants have identified two (2) predominate strand patterns from the blood of a pregnant woman which determine the sex of a fetus within a few weeks of conception.

2. Claims 1-20 are supported by adequate written description under 35 U.S.C. § 112, first paragraph.

The Examiner contends that the "approximately circular" or "polygonal" or "generally linear" language used in claims 1-20 is not supported by an adequate written description. According to the Examiner, "In absence of written description of the source of the diagrams, it is not clear how the particular shapes of the DNA complex of human blood samples can be correlated to any disease or determining the sex of a fetus". Applicant contends that this rejection is misplaced. The figures disclose shapes which applicant and any layperson would regard as "approximately circular" or "polygonal" or "generally linear", and hence the written description supports the claim language. Knowledge of the source of the diagrams will not help at all in this regard. The citations given by the Examiner to support this rejection are inapposite, one dealing with DNA structures (Fiers) and one dealing with enablement (Vas-Cath). The Examiner has simply not met his burden of articulating why the "approximately circular" or

"polygonal" or "generally linear" language used in claims 1-20 is not supported by the drawings which demonstrate the recited characteristics.

3. Claims 1-6 and 9-20 are clear and definite under 35 U.S.C. § 112, second paragraph.

The Examiner contends that the phrase "approximately circular or polygonal, or that the sex of the fetus is male if the shape of the strand pattern is generally linear or generally linear in combination with at least one elongated ring." is fraught with relative terms and is indefinite. The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. Seattle Box Co., v. Industrial Crating & Packing, Inc., 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. For example, the term "substantially" is often used in conjunction with another term to describe a particular characteristic of the claimed invention. It is a broad term. In re Nehrenberg, 280 F.2d 161, 126 USPQ 383 (CCPA 1960). The court held that the limitation "to substantially increase the efficiency of the compound as a copper extractant" was definite in view of the general guidelines contained in the specification. In re Mattison, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). The court held that the limitation "which produces substantially equal E and H plane illumination patterns" was definite because one of ordinary skill in the art would know what was meant by "substantially equal." Andrew Corp. v. Gabriel Electronics, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988). Here the terms "approximately circular or polygonal, or that the sex of the fetus is male if the shape of the strand

pattern is generally linear or generally linear in combination with at least one elongated ring" are plain terms on their face, and unambiguous because they are geometric shapes which, when deviated too much, become other shapes.

* * * * *

For the reasons set forth herein, it is believed that this application clearly and patentably distinguishes over the prior art and is in proper condition for allowance.

Reversal is respectfully requested.

Respectfully submitted,

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APPENDIX A: Claims Under Appeal

1. A method of determining the sex of a fetus comprising:

a. mixing a sample of blood from a pregnant woman with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

1) preparing approximately one (1) volume of Tris-buffer;

2) adding approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately one (1) volume of Tris-buffer to produce a buffer diluted phenol; and

3) adding approximately two (2) volumes of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately a half (½) volume of chloroform and approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately twelve and a half (12½) volumes of freshly made 20% acid alcohol on a slide;

i. adding a blood cell sample consisting of approximately one fifth (1/5) volume of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. determining that the sex of the fetus is female if the shape of the strand pattern is approximately circular or polygonal, or that the sex of the fetus is male if the shape of the strand pattern is generally linear or generally linear in combination with at least one elongated ring.

2. A method of determining the sex of a fetus comprising:

a. mixing a sample of blood from a pregnant woman with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

1) preparing approximately 5 µl of Tris-buffer;

2) adding approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately 5.0 μl of Tris-buffer to produce a buffer diluted phenol; and

3) adding approximately 10 μl of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately 2.5 μl of chloroform and approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately 25 μl of freshly made 20% acid alcohol on a slide;

i. adding a blood cell sample consisting of approximately 1.0 μl of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. determining that the sex of the fetus is female if the shape of the strand pattern is approximately circular or polygonal, or that the sex of the fetus is male if the shape of the strand pattern is generally linear or generally linear in combination with at least one elongated ring.

3. The method of claim 1 or 2 in which the Tris-buffer consists of 0.5 M Tris, 0.2 M EDTA, 0.6% NaCl, having a pH of between 10.3 and 10.4.

4. The method of claim 1 or 2 in which the step of centrifuging the first blood cell mixture is performed for approximately ten (10) minutes at 11,000 rpm.

5. The method of claim 1 or 2 in which the step of centrifuging the second blood cell mixture is performed for approximately fifteen (15) minutes at 11,000 rpm.

6. The method of claim 1 or 2 in which the step of cooling the second liquid phase is performed by placing the second liquid phase on ice for approximately fifteen (15) minutes.

7. A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of blood from a human donor with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

1) preparing approximately one (1) volume of Tris-buffer;

2) adding approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately one (1) volume of Tris-buffer to produce a buffer diluted phenol; and

3) adding approximately two (2) volumes of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately a half (½) volume of chloroform and approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately twelve and a half (12½) volumes of freshly made 20% acid alcohol on a slide;

i. adding a blood cell sample consisting of approximately one fifth (1/5) volume of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. using the strand pattern to detect a change in the body of the human donor.

8. A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of the human blood with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

1) preparing approximately 5 μl of Tris-buffer;

2) adding approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately 5.0 μl of Tris-buffer to produce a buffer diluted phenol; and

3) adding approximately 10 μl of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately 2.5 μl of chloroform and approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately 25 μl of freshly made 20% acid alcohol on a slide; and

i. adding a blood cell sample consisting of approximately 1.0 μl of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. using the strand pattern to detect a change in the body of the human donor.

9. A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of blood from a human donor with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

1) preparing approximately one (1) volume of Tris-buffer;

2) adding approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately one (1) volume of Tris-buffer to produce a buffer diluted phenol; and

3) adding approximately two (2) volumes of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately a half (½) volume of chloroform and approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately twelve and a half (12½) volumes of freshly made 20% acid alcohol on a slide;

i. adding a blood cell sample consisting of approximately one fifth (1/5) volume of the cooled second liquid phase onto the center of the top surface of the acid alcohol

sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. detecting a change in the body of the human donor if the strand pattern comprises a strand which is not smooth throughout most of the strand's length.

10. A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of blood from a human donor with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

1) preparing approximately one (1) volume of Tris-buffer;

2) adding approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately one (1) volume of Tris-buffer to produce a buffer diluted phenol; and

3) adding approximately two (2) volumes of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately a half (½) volume of chloroform and approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately twelve and a half (12½) volumes of freshly made 20% acid alcohol on a slide;

i. adding a blood cell sample consisting of approximately one fifth (1/5) volume of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. detecting a change in the body of the human donor if the strand pattern comprises a strand which has a plurality of beads and a substantial discontinuity with associated branching.

11. A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of blood from a human donor with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

1) preparing approximately one (1) volume of Tris-buffer;

2) adding approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately one (1) volume of Tris-buffer to produce a buffer diluted phenol; and

3) adding approximately two (2) volumes of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately a half (½) volume of chloroform and approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately twelve and a half (12½) volumes of freshly made 20% acid alcohol on a slide;

i. adding a blood cell sample consisting of approximately one fifth (1/5) volume of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. detecting a change in the body of the human donor if the strand pattern comprises a strand which has a looped portion and a substantial discontinuity with associated branching.

12. A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of the human blood with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

1) preparing approximately 5 µl of Tris-buffer;

2) adding approximately 2.5 µl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately 5.0 µl of Tris-buffer to produce a buffer diluted phenol; and

3) adding approximately 10 µl of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately 2.5 µl of chloroform and

approximately 2.5 µl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately 25 µl of freshly made 20% acid alcohol on a slide; and

i. adding a blood cell sample consisting of approximately 1.0 µl of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. detecting a change in the body of the human donor if the strand pattern comprises a strand which is not smooth throughout most of the strand's length.

13. A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of the human blood with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

1) preparing approximately 5 µl of Tris-buffer;

2) adding approximately 2.5 µl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately 5.0 µl of Tris-buffer to produce a buffer diluted phenol; and

3) adding approximately 10 µl of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately 2.5 μl of chloroform and approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately 25 μl of freshly made 20% acid alcohol on a slide; and

i. adding a blood cell sample consisting of approximately 1.0 μl of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. detecting a change in the body of the human donor if the strand pattern comprises a strand which has a plurality of beads and a substantial discontinuity with associated branching.

14. A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of the human blood with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

1) preparing approximately 5 μl of Tris-buffer;

2) adding approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the

approximately 5.0 μl of Tris-buffer to produce a buffer diluted phenol; and

3) adding approximately 10 μl of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately 2.5 μl of chloroform and approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately 25 μl of freshly made 20% acid alcohol on a slide; and

i. adding a blood cell sample consisting of approximately 1.0 μl of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. detecting a change in the body of the human donor if the strand pattern comprises a strand which has a looped portion and a substantial discontinuity with associated branching.

15. The method of claim 7, 8, 9, 10, 11, 12, 13 or 14 in which the Tris-buffer consists of 0.5 M Tris, 0.2 M EDTA, 0.6% NaCl, having a pH of between 10.3 and 10.4.

16. The method of claim 7, 8, 9, 10, 11, 12, 13 or 14 in which the step of centrifuging the first blood cell mixture is performed for approximately ten (10) minutes at 11,000 rpm.

17. The method of claim 7, 8, 9, 10, 11, 12, 13 or 14 in which the step of centrifuging the second blood cell mixture is performed for approximately fifteen (15) minutes at 11,000 rpm.

18. The method of claim 7, 8, 9, 10, 11, 12, 13 or 14 in which the step of cooling the second liquid phase is performed by placing the second liquid phase on ice for approximately fifteen (15) minutes.

19. A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of blood from a human donor with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

1) preparing approximately one (1) volume of Tris-buffer;

2) adding approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately one (1) volume of Tris-buffer to produce a buffer diluted phenol; and

3) adding approximately two (2) volumes of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately a half (½) volume of chloroform and approximately a half (½) volume of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately twelve and a half (12½) volumes of freshly made 20% acid alcohol on a slide;

i. adding a blood cell sample consisting of approximately one fifth (1/5) volume of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. using the strand pattern to detect a change in the body of the human donor.

20. A method of detecting a change in the body of a human being caused by a pathological condition, comprising:

a. mixing a sample of the human blood with an anticoagulant to form an anti-coagulated blood mixture;

b. centrifuging the anti-coagulated blood mixture in order to separate the plasma from the blood cells;

c. preparing a first blood cell mixture in accordance with the following steps:

1) preparing approximately 5 μl of Tris-buffer;

2) adding approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer, to the approximately 5.0 μl of Tris-buffer to produce a buffer diluted phenol; and

3) adding approximately 10 μl of the blood cells to the buffer diluted phenol;

d. centrifuging the first blood cell mixture to form a first liquid phase and first blood cell debris;

e. preparing a second blood cell mixture by mixing the centrifuged first blood cell mixture and first blood cell debris with approximately 2.5 μl of chloroform and approximately 2.5 μl of Tris-buffer saturated phenol, prepared by mixing re-distilled phenol with Tris-buffer;

f. centrifuging the second blood cell mixture to form a second liquid phase and second blood cell debris;

g. cooling the second liquid phase and second blood cell debris thereby causing the structural components of the DNA complex within the second liquid phase to aggregate;

h. placing an acid alcohol sample consisting of approximately 25 µl of freshly made 20% acid alcohol on a slide; and

i. adding a blood cell sample consisting of approximately 1.0 µl of the cooled second liquid phase onto the center of the top surface of the acid alcohol sample and allowing both samples to dry at room temperature without any disturbance, whereby an aggregate of the DNA complex deposits a strand pattern on the slide; and

j. using the strand pattern to detect a change in the body of the human donor.